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Nonconformances

Quality Implementing Procedure ID: OSTI-LLNL-QIP-15.0, Rev.0, Mod.0

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NONCONFORMANCES

Quality Implementing Procedure ID: OSTI-LLNL-QIP-15.0, Rev. 0, Mod. 0 *Effective:* 2/25/05

1. PURPOSE

This Quality Implementing Procedure (QIP) establishes a standard process for the Office of Science & Technology and International (OSTI)-Lawrence Livermore National Laboratory (LLNL) Project to identify, report, control, disposition, and verify correction of nonconforming conditions.

This procedure also establishes the interface between the OSTI-LLNL Project and the Office of Civilian Radioactive Waste Management (OCRWM) OSTI to execute this process.

2. SCOPE

This QIP applies to nonconforming data, specimens and samples that result from activities specified in governing plans or procedures subject to the requirements of the OSTI-LLNL Quality Assurance Plan (QAP) which implements the U.S. Department of Energy (DOE) OCRWM *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P. This procedure has been prepared in accordance with OSTI-LLNL-QIP-5.0, *Preparation of the Quality Assurance Plan and Quality/Technical Implementing Procedures.*

This QIP applies to the activities of the OSTI-LLNL nonconformance Initiator, Dispositioner, Quality Assurance (QA) Manager (or designee), Principal Investigator (PI), Deputy Project Manager (DPM), and/or Project Manager (PM) involved in these activities.

3. PROCEDURE

3.1 Initiating Nonconformances

A nonconformance is a deficiency in characteristic or record that renders the quality of an item or sample unacceptable or indeterminate.

3.1.1 When a nonconforming condition is identified, the **Initiator** shall:

A. Notify the PI of the nonconforming condition.

B. In consultation with the QA Manager, initiate a Nonconformance Report (NCR), in accordance with instructions provided in Attachment 1. Obtain a NCR Number from the QA Manager (Block1), and identify the OSTI LLNL Task Affected (Block 2). Print name, sign, and date the NCR (Block 3).

Provide a detailed description of the nonconforming condition (Block 4) including the requirement violated (e.g., procedure/plan, and revision, equipment/hardware name, location, supplier, etc.), and the governing procedure number and revision number (Block 5).

C. Perform one of the following:

1. Apply a Hold Tag (Attachment 2) to prevent further processing, installation, or inadvertent use of the item or sample and enter number of Hold Tags applied on the NCR (Block 6).
2. Ensure nonconforming items or samples are segregated, when practical, by placement in a clearly identified hold area.
3. If Hold Tag application or segregation is impractical or impossible (e.g., due to physical limitations such as size, weight; access limitations; or stage of processing), employ other means to readily identify the nonconforming items or samples to preclude inadvertent use. The method used must not adversely affect the end use of the item or sample. The identification shall be legible, easily recognizable, and include the NCR number.

D. Forward the NCR to the PI for action, and provide a copy to the QA Manager for tracking purposes.

3.1.2 The **PI** (or designee) shall review the description of the nonconforming condition, including the requirement violated in order to evaluate/validate that the nonconforming condition exists and document this validation on the NCR, as follows:

A. If invalid, check the "Invalid" box (Block 7), attach justification on the NCR Continuation Page (Attachment 1, page 2), remove any hold tags, and indicate Hold Tags removed (Block 6), and print name, sign and date (Block 7).

B. If valid, check the "Valid" box (Block 7), determine whether the nonconforming condition is quality-related (Q) (subject to QAP requirements) or Non-Q related, signify such by checking the Q, or Non-Q box, and print name, sign and date (Block 7).

C. If at any time during the processing of the NCR additional information is obtained that would render the NCR invalid, remove the Holding tag(s), if applicable, indicate this in Block 6, and forward the NCR to the QA Manager to process in accordance with Section 3.1.3 B.

D. Forward the updated NCR to the PI (if a designee is performing the validation) and the QA Manager.

3.1.3 QA Manager (or designee):

A. After assigning the NCR a number (see Section 3.1.1.B), log the number into a NCR Log. The NCR number is a unique identifier, used to ensure tracking of each NCR, of the following format "OSTI-LLNL-NCR-XX-YYY" where OSTI-LLNL-NCR denotes the project designator of the nonconformance, XX indicates the current fiscal year (e.g., 03, 04, etc.), and YYY is a three digit sequential number.

B. Upon receipt of a valid or invalid NCR:

- Update the NCR Log.
- If invalidated, forward a copy of the NCR to the NCR Initiator, and submit the NCR to the Records Coordinator for submittal to the Records Center (RC) in accordance with Section 4.0

3.2 Dispositioning NCR's

3.2.1 PI:

Based on the nonconforming condition description, assign a technical staff member to be the Dispositioner (an individual with demonstrated competence in the specific technical area and with an adequate understanding of the requirements and access to pertinent background information) to be responsible for evaluating nonconforming conditions and preparing recommended dispositions. The PI may perform the tasks assigned to the Dispositioner.

3.2.2 Dispositioner:

A. Evaluate and determine proposed actions necessary to resolve the nonconforming condition.

B. Provide recommended disposition in Block 8 of the NCR by marking the appropriate box:

1. For items, mark "Rework", "Repair", "Use-As-Is", or "Reject/Scrap."

2. For samples, mark "Use-As-Is", "Limited Use", or "Discard."

C. Provide Justification/Comments relative to the recommended disposition on a NCR Continuation Page (Attachment 1, page 2), as follows:

1. A "Limited Use" disposition identifies that samples have a limited and controlled use; this use is specified as part of the disposition and controlled by application of a "Limited-Use-Tag" (Attachment 3), as directed by the disposition.

2. Items that do not meet the original requirements that are dispositioned "Use-As-Is" or "Repair" will be subjected to control measures commensurate with those applied to the original item.

   The technical justification for the acceptability of a nonconforming item that has been dispositioned "Repair" or "Use-As-Is" shall be specified, and submitted to the OCRWM OSTI for acceptance prior to implementing the disposition.

3. During evaluation of nonconforming condition and determination of disposition, determine if there are any impacts to Waste Isolation and Safety, Licensing, or data, check "Yes" or "No" (Block 9). If it is determined that an impact exists, provide appropriate directions/instructions within the disposition of the NCR, as appropriate.

4. If changes to specifying documents are required to reflect the "Repair" or "Use-As-Is" condition, the disposition shall require action to change the specifying document to reflect the accepted nonconforming condition.

5. Documents or record changes required by disposition of the nonconforming condition shall be identified in the NCR, and when each document or record is changed, the justification for the change shall identify the NCR number. The NCR shall not be closed prior to changes to the affected documents being completed or implemented in accordance with an approved change process (e.g., OSTI-LLNL-QIP-5.0).

6. Include requirements to re-examine repaired or reworked items in accordance with original acceptance criteria unless alternate acceptance criteria are specified in the disposition.

7. If, in review of the NCR, it is determined that only a specific portion of an item or sample is nonconforming, identify the specific portion so that work may proceed on the remaining non-affected portions.

D. Evaluate the nonconforming condition for "Conditional Release." Although not a disposition, a "Conditional Release" requires documented justification. A Conditional Release may be used when additional work effort is necessary to provide information required for determining appropriate disposition. When establishing a "Conditional Release", the Dispositioner shall consider such factors as:

1. Whether the nonconforming item can be removed without any unacceptable damage to associated item(s)
2. Whether the item remains accessible for any required subsequent inspections/tests
3. Any limitations of use
4. Any necessary tracking identification
5. Whether the nonconforming item can be used safely.

E. If a Conditional Release is proposed, check the "Yes" box in Block 8 of the NCR and provide justification and any limitations on a NCR Continuation Page (Attachment 1, page 2.)

F. Print name, sign, and date Block 10 of the NCR for recommended dispositions or Conditional Releases recommendations.

3.2.3 The **PI** or **PM/DPM** (if the PI is the Dispositioner) shall review the recommended disposition or Conditional Release for approval and shall:

A. Ensure OCRWM OSTI acceptance has been obtained for any nonconformances dispositioned as "Repair" (items only) or "Use-As-Is" (items, samples, specimens, data) (as required in Section 3.2.2 C. 2)

B. Return the NCR to the Dispositioner for resolution if the recommended disposition or "Conditional Release" is found to be unacceptable.

C. Upon resolution, or if the disposition is found to be acceptable, print name sign, and date Block 10. For Conditional Release, print name, sign, and date the attachment, as well as Block 10.

D. Forward the dispositioned NCR to the QA Manager.

3.2.4 The **QA Manager** (or designee) shall review the disposition or Conditional Release for a Q-related NCR, to ensure that applicable quality requirements have been incorporated and:

A. If the disposition or Conditional Release for a Q-related NCR, is found to be unacceptable, return the NCR to the PI or Deputy PM for resolution.

B. Upon resolution, or if the disposition is found to be acceptable, print name,

sign, and date Block 11 of the NCR.

C. If the Conditional Release for a Q-related NCR is found to be acceptable, print name and initial and date the Conditional Release continuation page. Coordinate annotation of the conditions of the Conditional Release on the nonconforming identification medium used (Attachments 2 and 3.)

D. For a Q-related NCR, determine the need for additional corrective action in accordance with OSTI-LLNL-QIP-16.0, *Condition Reporting and Resolution* and if required, initiate a Condition Report (CR). Identify the CR number, and check the "Yes" box in Block 11. If it is determined that additional corrective action is not required, check "No" in Block 11 and attach a brief statement recording logic used in making the determination on a NCR Continuation Page (Attachment 1, page 2.)

E. Update the NCR working file with a copy of the NCR and update the NCR Log regarding the status of the NCR.

F. Forward the NCR to the PI for implementation of the disposition or Conditional Release.

3.3 Implementing the Disposition

3.3.1 The **PI** (or designee) shall complete the required actions in accordance with the approved disposition or Conditional Release and shall:

A. Signify completion of the disposition by printing name, signing, and dating Block 12 of the NCR. For Conditional Release, provide documentation as required by the Conditional Release, as appropriate.

B. Forward the NCR to the PI or, if the Dispositioner is the PI, to the Deputy PM for concurrence signature/date, and then to the QA Manager for NCR Closure.

3.4 NCR CLOSURE

3.4.1 The **QA Manager** (or designee) shall review the disposition documentation, verify that all actions required by the disposition have been completed, and sign Block 12 if in agreement. The QA manager shall:

A. Coordinate with the PI the removal of any Hold Tag(s) that were placed and document the number of Hold Tags removed in Block 6.

B. Determine the trend information for the NCR in Block 13 from the *QA Trend Analysis Guidelines* identified in OSTI-LLNL-QIP-16.0.

C. Ensure that procedural requirements have been met and that the NCR is complete (e.g. printed name, signatures, date, etc.; spaces on the

NCR may be completed or marked N/A as appropriate to the disposition). Final review with printed name, signature and date (Block 14) indicates that all required actions have been completed as necessary, and all required NCR attachments are included.

D. Contact responsible personnel for resolution if questions arise during the course of the review.

E. Update the NCR Log and transmit the NCR to the Records Coordinator for submittal to the RC in accordance with Section 4.0.

3.5 Revising/Correcting NCRs

3.5.1 If, during the course of processing an open NCR, it is determined that the description of the nonconforming condition or disposition, needs to be revised, the **OSTI-LLNL Personnel** shall process the revision as follows:

A. Clearly describe/annotate what is being revised (e.g., description of nonconforming condition, disposition, etc.) and place a revision number inside a delta adjacent to the revision. Initial and date the revision.

B. Annotate all previous pages of the NCR with the revision number, within the delta, adjacent to the NCR number.

C. Reprocess the proposed revision through the appropriate steps outlined in Sections 3.1 through 3.3.

D. Ensure that revisions to NCRs are approved as appropriate for the revision being made.

3.5.2 If, after closure of a NCR and processing to the RPC, it is determined that a revision is necessary, the **OSTI-LLNL Personnel** shall process the revision by initiating a new NCR in accordance with this procedure and reference the original NCR in the description of the nonconforming condition. A record change shall be forwarded to the Records Coordinator to annotate the new NCR number on the old NCR and notify the RC, in accordance with OSTI-LLNL-QIP-17.0, *Records Management.*

3.5.3 Editorial corrections shall be made by the NCR Initiator or the PI. Editorial corrections are made by drawing a single line through the subject matter to be changed, annotating the correction, and applying initials and dating the correction. Editorial corrections are not identified by deltas as required for revisions but shall be distributed as a change to the NCR.

4. RECORDS

The records listed below shall be collected and submitted to the RC in accordance with OSTI-LLNL-QIP-17.0, as individual records or included in a records package, as specified.

4.1 QA Records

Records package:

Completed Q-related NCRs, including NCR Continuation Pages, and relevant correspondence

4.2 Non-QA Long-Term Records

Records package:
Completed Non-Q NCRs, NCR Continuation Pages, and relevant correspondence

4.3 Non-QA Short Term Records (three years or less retention)

None.

5. RESPONSIBILITIES

5.1 The **Project Manager/Deputy Project Manager** is responsible for approving the recommended disposition, and approving the completion of actions taken to implement the disposition when the Dispositioner is the PI.

5.2 The **PI** is responsible for designating a qualified technical staff member to validate the existence of a nonconformance and recommend a disposition for the nonconformance, and for approving the recommended disposition and completion of actions taken to implement the disposition. The PI may perform the functions of the Dispositioner.

5.3 The **NCR Initiator** is responsible for notifying the PI of the existence of a nonconforming item or sample and documenting the nonconformance on a NCR in accordance with this procedure.

5.4 The **Dispositioner** is responsible for validating the existence of a nonconformance, recommending a disposition for the nonconformance, implementing the approved disposition, and documenting these actions on a NCR and obtaining appropriate approvals in accordance with this procedure.

5.5 The **QA Manager** (or designee) is responsible for assigning a NCR

number, maintaining a NCR log, verifying completion of the disposition actions taken to the NCR, identifying if additional corrective actions are required, and initiating a CR if required. The QA Manager is responsible for trending the NCR and ensuring all NCR documentation is complete and NCR records are submitted to the RC.

6. ACRONYMS AND DEFINITIONS

6.1 Acronyms

DOE	U.S. Department of Energy
DPM	Deputy Project Manager
LLNL	Lawrence Livermore National Laboratory
NCR	Nonconformance Report
OCRWM	Office of Civilian Radioactive Waste Management
OSTI	Office of Science & Technology and International
PM	Project Manager
Q	Quality
QA	Quality Assurance
QAP	Quality Assurance Plan
QARD	Quality Assurance Requirements and Description
RC	Records Center

6.2 Definitions

Conditional Release: Documented authorization to continue work on or continue using a nonconforming item or sample prior to implementing an approved disposition of a nonconforming condition. Conditional Release may be used to direct additional work activity necessary to provide information required to develop/determine a comprehensive disposition.

Discard: The disposition that is authorized when a nonconforming sample is considered unacceptable for scientific investigation.

Dispositioner: The individual responsible for evaluating nonconforming conditions and preparing recommended dispositions and who has an adequate understanding of the requirements and access to pertinent background information.

Indeterminate: The status of a nonconforming condition when its acceptability cannot be ascertained with a reasonable amount of effort.

Item: An all inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit (QARD).

Limited Use: The disposition that establishes limitations for use of

nonconforming samples.

Nonconformance: A deficiency in characteristic or record that renders the quality of an item, sample, specimen or data unacceptable or indeterminate.

Nonconformance Report (NCR): A form used for reporting nonconforming conditions of items, samples, specimens or data.

Repair: The process of restoring an item to a condition such that the capability of an item to function reliably and safely is unimpaired even though that item still does not conform to the original requirement (QARD).

Rework: The process by which an item is restored to original specifications by completion or correction (QARD).

Sample: Rock, water or other geologic sample.

Scrap/Reject: The disposition that is authorized when the nonconforming item cannot be reworked or repaired and is considered unacceptable for its intended use. Reject may include the return of an item to the original supplier.

Specimen: Material, typically metal, in various configurations, (e.g., welded, coated, annealed, heat treated, etc.,) and/or treatments.

Use-As-Is: Disposition permitted for a nonconforming item when it can be established that the item, sample, specimen or data is satisfactory for its intended use and no additional action is required.

7. REFERENCES

DOE/RW-0333P, *Quality Assurance Requirements and Description*

OSTI-LLNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures*

OSTI-LLNL-QIP-12.0, *Control of Measuring and Test Equipment and Calibration Standards*

OSTI-LLNL-QIP-16.0, *Condition Reporting and Resolution*

OSTI-LLNL-QIP-17.0, *Records Management*

8. ATTACHMENTS

Attachment 1: Nonconformance Report (NCR)

Attachment 2: Hold Tag

Attachment 3: Limited-Use-Tag

9. REVISION HISTORY

2/25/05 Revision 0, Modification 0:
Initial issue.

10. APPROVALS

Preparer: Leigh Gouveia 2/25/05
Date:

Technical Reviewer: QINHONG HU 2/25/05
Date:

QA Reviewer: VICTOR J. BARISH JR 2/25/05
Date:

Project Manager: DAVID B. MCCALLEN 2/25/05
Date:

OSTI-LLNL
NONCONFORMANCE REPORT

QA:
Page 1 of :

NCR Initiation

1. NCR. No. _____

2. OSTI-LLNL Task Affected: _____

3. Initiator: _____ _____ _____
Print Name Signature Date

4. Detailed Description of Nonconformance (Use Continuation Page if Necessary)

5. Governing Procedure, Rev./Mod. No.:

6. Number of Hold Tags Applied: _____
Number of Hold Tags Removed: _____

7. Validation

_ Invalid[1] _ Valid PI (or designee) _____ _____ _____
_ Q _ Non-Q Print Name Signature Date

[1]Provide justification on a Continuation page

8. Disposition (PI or designee)

_ Rework[2] _ Repair[3] _Use-As-Is[3]
_ Limited Use _ Discard _Reject/Scrap

[2] Requires re-examination requirements and acceptance criteria.
[3] Requires OSTI acceptance and change to specifying the document(s).

Conditional Release: _ Yes _ No
(If Yes, attach justification on a Continuation Page.)

9. Impacts Waste Isolation, Safety, Licensing, or Data
_Yes _No

10. Dispositioner Recommendation/Approval

Recommended By: _____ _____ _____
Print Name Signature Date

Approved By: _____ _____ _____
PI or Deputy PM Print Name Signature Date

11. Disposition QA Review

Corrective Action Required: _ Yes _ No
Corrective Action/CR No. _____
(For Q-related NCRs, attach justification statement on a Continuation Page)

QA Manager (or designee): _____ _____ _____
Print Name Signature Date

12. Completion of Disposition

Dispositioner: _____ _____ _____
Print Name Signature Date

PI or Deputy PM: _____ _____ _____
Print Name Signature Date

QA Manager (or designee): _____ _____ _____
Print Name Signature Date

13. QA Trend Information

14. Final Review:

QA Manager: _____ _____ _____
Print Name Signature Date

OSTI-LLNL
NONCONFORMANCE REPORT
CONTINUATION PAGE

QA:
Page of:

1. NCR. No. _____

EXAMPLE

NCR INSTRUCTIONS

Initiator:

1. Obtain NCR Number from the QA Manager and enter NCR Number.
2. Identify the OSTI-LLNL task in which the NCR was found.
3. Print name, sign, and date initiated.
4. Describe the nonconformance, including requirement violated and item, specimen, data or sample affected.
5. Identify governing procedure ID/Rev./Mod. Number.
6. Record number (count) of Hold Tags applied. **PI (or designee)**:
7. Check "Valid" or "Invalid, and justification on a Continuation Page." If valid, check if "Q" or "Non-Q," Print name, sign, and date.

Dispositioner (PI or designee):

8. Check appropriate disposition box. For items: check "Rework, Repair, Use-As-Is, or Reject/Scrap." For samples, specimen or data: check "Use-As-Is, Limited Use, or Discard." Provide disposition justification/comments on a Continuation Page. Any items that are dispositioned as "Repair or Use-As-Is," require OSTI approval
   Check "Yes" if determined to be a Conditional Release; otherwise check "No." If "Yes" is checked, provide justification/comments on a Continuation Page and obtain appropriate reviews/approvals.
9. Check "Yes" if nonconformance impacts Waste Isolation and Safety, Licensing, or Data and provide appropriate direction/instruction within the NCR; otherwise check "No."

Dispositioner (PI or designee) and Approver (PI or Deputy PM):

10. Print name, signature and date for person recommending disposition.
    Print disposition Approver's name, signature, and date. **QA Manager (or designee)**:
11. For a Q-related NCR, check "Yes" if Corrective Action per OSTI-LLNL-QIP-16.0 is required. If not, check "No" and provide justification on a Continuation Page. If "Yes," initiate a Condition Report (CR) and provide CR number. Provide name, sign, and date.

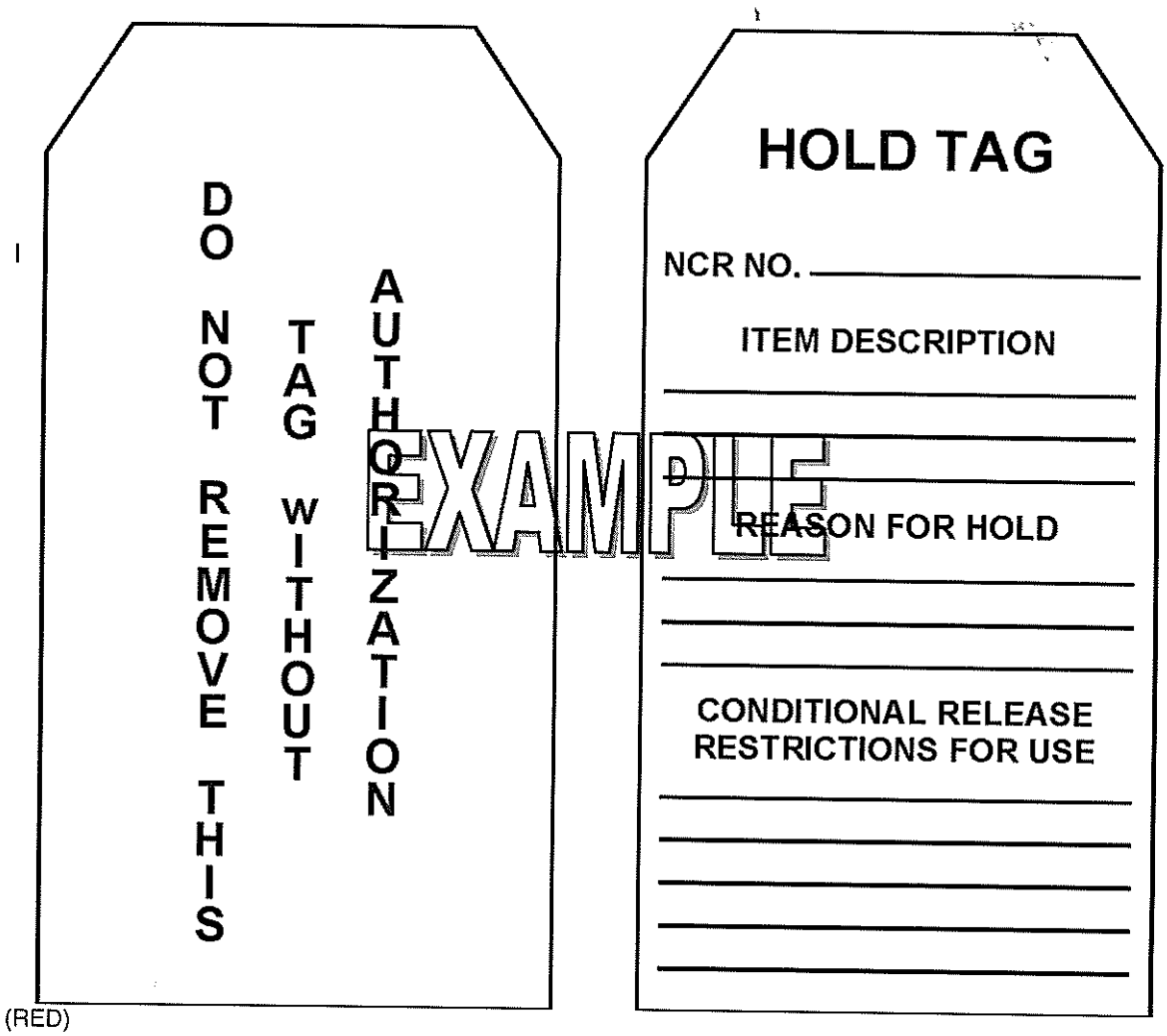
Dispositioner:

12. When disposition actions have been completed, provide name, sign, and date of completion. **PI or Deputy PM/QA Manager (or designee)**:

12. Determine if in agreement with disposition completion. Print name, sign, and date and record the number (count) of Hold Tags removed in Block 6.

QA Manager:

13. Enter QA Trend Information (per OSTI-LLNL-QIP-16.0).
14. Determine that OSTI-LLNL-QIP-15.0 procedural requirements have been completed and all required documents are included. Print name, sign, and date.


DO NOT REMOVE THIS TAG WITHOUT AUTHORIZATION
EXAMPLE
HOLD TAG
NCR NO.
ITEM DESCRIPTION
REASON FOR HOLD
CONDITIONAL RELEASE
RESTRICTIONS FOR USE

(RED)

SAMPLE/SPECIMEN LIMITED-USE-TAG

NCR NO.__ DATE: _____

SAMPLE/SPECIMEN DESCRIPTION:

_____

_____

SAMPLE/SPECIMEN ID # _____

LIMITED USE RESTRICTIONS:

_____

_____

_____

_____

_____

ORGANIZATION/DATE

(YELLOW)